

James Bickford (N.Y. Bar No. 5163498)
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20530
James.Bickford@usdoj.gov
Telephone: (202) 305-7632
Attorney for Defendant

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON**

JEREMY OLSEN,)
Plaintiff,)
v.)
ALEX M. AZAR II, in his official)
capacity as Secretary of Health and)
Human Services,)
Defendant.)

))
DEFENDANT'S REPLY
IN SUPPORT OF HIS
CROSS-MOTION
FOR SUMMARY JUDGMENT
)
Case No. 2:20-cv-374 (SMJ)
January 28, 2021
Without Oral Argument

INTRODUCTION

This Court is reviewing a decision of the Medicare Appeals Council, which denied coverage for plaintiff's continuous glucose monitor (CGM) because the device in question was not accurate enough to replace a blood glucose monitor. The Appeals Council concluded that the device therefore was not durable medical equipment within the meaning of the Medicare statute and regulations. To date, four district courts have rejected the Secretary's interpretation, and the Secretary has now

1 proposed a rule that would deem continuous glucose monitors to be durable medical
2 equipment whether or not they are accurate enough to replace a blood glucose
3 monitor. The first question that this Court should address on these cross-motions
4 for summary judgment is whether the Secretary's present interpretation of the
5 Medicare statute and regulations is permissible, with the appropriate amount of
6 deference to the agency's view of the statutes and regulations that it administers.

7 If the Court concludes that the decision of the Medicare Appeals Council was
8 *substantively* valid, then it can proceed to consider whether CMS Ruling 1682-R
9 was *procedurally* valid. But it makes no sense for the Court to address the
10 procedural question first, as plaintiff urges it to do (for reasons that are somewhat
11 obscure). If the decision of the Appeals Council and CMS Ruling 1682-R are
12 substantively valid, but CMS Ruling 1682-R is procedurally invalid, then the
13 appropriate remedy is for this Court to remand to the agency for a decision on
14 plaintiff's claim without reference to the invalid ruling. Despite plaintiff's insistence
15 to the contrary, a procedural error in the issuance of CMS Ruling 1682-R would not
16 and could not lead to a substantive reversal of the Appeals Council's decision in this
17 case.

18
19
20

ARGUMENT

A. The Appeals Council's decision was substantively valid.

In his cross-motion for summary judgment the Secretary explained that under the terms of CMS Ruling 1682-R, which the Medicare Appeals Council followed here, CGMs are only covered if they are accurate enough to be “used for making diabetes treatment decisions, such as changing one’s diet or insulin dosage based solely on the readings of the CGM.” CMS Ruling 1682-R at 7. Less accurate CGMs are not covered. It was not arbitrary or otherwise unlawful for the Secretary to make this distinction. To the contrary, it is entirely reasonable for the Secretary to encourage the use of the more accurate devices.

The Secretary's view has been that the "medical purpose" of a CGM is to enable a beneficiary to make treatment decisions, and that less-accurate CGMs do not serve that medical purpose. *See* CMS Ruling 1682-R at 9 ("The medically necessary function of a glucose monitor is to inform the patient about their glucose level so that they can make diabetes treatment decisions such as changing their diet or insulin dosage."). CMS Ruling 1682-R sets out a coverage standard under which more accurate CGMs are covered, and less accurate CGMs are not. That determination is reasonable, lawful, and entitled to deference from this Court.

19 In his opposition and reply, plaintiff simply repeats arguments made in his
20 motion for summary judgment: chiefly, that the Secretary's interpretation is arbitrary

1 or contrary to the Medicare statute and regulations. It was not arbitrary or otherwise
2 unlawful for the Secretary to make the distinction at the heart of CMS Ruling 1682-
3 R and the Appeals Council decision at issue here.

4 **B. The procedural claim should be dismissed, has been waived, and**
5 **could not lead to the only relief sought here.**

6 Plaintiff's procedural claim under 5 U.S.C. § 706(2)(D) should be dismissed.
7 If the claim is not dismissed, it has nonetheless been waived because it was not raised
8 in the administrative process, as the Secretary explained in his cross-motion. *Zieroth*
9 *v. Azar*, 2020 WL 5642614, at *3 (N.D. Cal. Sept. 22, 2020) ("[T]he Court finds the
10 procedural challenge [to CMS Ruling 1682-R] asserted by Zieroth was waived"
11 when it was not raised before the agency.); *see Lands Council v. McNair*, 629 F.3d
12 1070, 1076 (9th Cir. 2010) ("A party forfeits arguments that are not raised during
13 the administrative process."). And even if the Court determines that this procedural
14 claim should not be dismissed and was not waived, a procedural error would not
15 give this Court license to make a *de novo* coverage determination itself, but only to
16 remand to the agency for a new decision without reference to CMS Ruling 1682-R.

17 Plaintiff argues that a decision on his procedural claim would have more
18 impact, because CMS Ruling 1682-R would otherwise remain in force. But that
19 argument completely misunderstands the posture of this case. This Court has
20 jurisdiction to review the decision of the Medicare Appeals Council, not CMS

1 Ruling 1682-R directly. However, the Court may consider both the substantive and
2 procedural validity of the CMS Ruling to the extent necessary to pass judgment on
3 the decision of the Appeals Council. If the Court finds CMS Ruling 1682-R to be
4 substantively invalid, then it may overturn the decision of the Appeals Council on
5 the merits. But if the Court finds CMS Ruling 1682-R to be procedurally invalid, it
6 does not follow that the Appeals Council has made a substantive error meriting
7 reversal: if the Appeals Council erred in relying on a procedurally invalid CMS
8 Ruling, then it should be given the chance to make a decision without reference to
9 that Ruling. *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1111 (D.C. Cir.
10 2014) (citing *Sec. & Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194, 201 (1947)
11 (“After the remand was made, therefore, the Commission was bound to deal with
12 the problem afresh, performing the function delegated to it by Congress.”)).

13 **CONCLUSION**

14 The Court should uphold the decision of the Medicare Appeals Council, enter
15 summary judgment in favor of the Secretary, and deny Plaintiff’s motion for
16 summary judgment.

Respectfully submitted,

JEFFREY BOSSERT CLARK
Assistant Attorney General

MICHELLE BENNETT
Assistant Director, Federal Programs Branch

/s/ James Bickford

JAMES BICKFORD

Trial Attorney (N.Y. Bar No. 5163498)

United States Department of Justice

Civil Division, Federal Programs Branch

1100 L Street, NW

Washington, DC 20530

James.Bickford@usdoj.gov

Telephone: (202) 305-7632

Facsimile: (202) 616-8470

Counsel for Defendant

Date: January 11, 2021